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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,130	05/17/2006	Rainer Sturmer	13111-00035-US	4511
23416 7590 12/12/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,130

Applicant(s)

STURMER ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 7-11 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-26 are pending in this application.

Claims 1-6, 11-20 are drawn to non-elected invention.

Response to Restriction Requirement

The election of group III, claims 21-26, with traverse in the Paper file 11/13/07 is hereby acknowledged. The traversal is on the basis that claims 7-10 are drawn to a process using dehydrogenase enzyme. Therefore, claims 7-10 are rejoined with the elected invention. Applicant also contends that product and a process of making therefore constitute a unity of invention, and therefore group II should be rejoined. This is not persuasive because while applicant is correct, the assertion applies only when the product is novel and unobvious. Claim 20 is drawn to a process of making an intermediate formula IV, not within the scope of the elected invention and therefore not examined herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10, 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks adequate support for the claims. The claims are drawn to a process wherein both R- and S-enantioselective dehydrogenase (DH) is used. The

specification discloses a process wherein S-enantioselective dehydrogenase is used, and S-isomer or excess thereof, of 3-methylamino-1-(thienyl-2-yl)propan-1-ol is made.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10, 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 depends from a non-elected claim. Claim 22 is drawn to a process of making the product but recites only a step of making the intermediate formula IV.

Therefore, claims 7-10, 21-26 are indefinite. Appropriate correction is required.

Claim 7 recites non-specific enzyme (E.C.) number while 8 recites 2 specific numbers. The numbers are not limitations under the US patent practice. By deleting the claims the rejection would be overcome.

Claim 23 recites the limitation "without being isolated." The claim depends from 21, which is from 7, which depends from 1, which recites the limitation. Therefore, claim 23 is a duplicate of 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10, 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuniyoshi et al., JP2003192681, and Dieter et al., DE10248479, individually, in

view of Wheeler, et al., J. Labeled Compds. Radiopharmaceut. (1995), Vol. 36(3), pp. 213-223, and Hummel, Adv. Biochem. Eng. Biotech. (1997), Vol. 58, pp. 145-184.

Applicant claims a process of making 3-methylamino-1-(thienyl-2-yl)propan-1-ol, comprising reacting thiophene with β -halopropionyl halide or an acryloyl halide in the presence of a Lewis acid to give 3-halo-1-(thienyl-2-yl)propan-1-one. Hydrogen halide is passed simultaneously or after the reaction is completed, but before the product is isolated. The 3-halo-1-(thienyl-2-yl)propan-1-one (fig. III, a ketone) is enantioselectively reduced with dehydrogenase (DH), the product (fig. IV, an alcohol) is optionally isolated and react with methylamine to form the final product. In preferred embodiments applicant claims the sources, the gene, and the E.C numbers of DH.

Determination of the scope and content of the prior art (MPEP 2141.01)

Kuniyoshi et al., and Dieter et al., teach similar processes of making 3-methylamino-1-(thienyl-2-yl)propan-1-ol. See the abstracts.

Wheeler, et al., teach a process of making 3-methylamino-1-(thienyl-2-yl)propan-1-ol, wherein HCl (hydrogen halide) is used.

Hummel teaches dehydrogenase for R- and/or S-enantioselective process of making alcohols from ketones. Hummel teaches the prerequisites for DH in the procedures (page 148-150); isolation of DH from microorganisms (page 164); specific DH for R and S enantioselective processes (page 164, and table 4); examples of substrates (page 163, and tables 5-6); and various sources of DH (page 146).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of the prior arts of Kuniyoshi et al., and Dieter et al., is that the prior arts do not use hydrogen halide and DH. Also, the prior arts do not teach the source, the gene, or the E.C number of DH.

Finding of prima facie obviousness--rational and motivation (MPEP 2142.2413)

However, Wheeler, et al., teach using HCl (hydrogen halide) and Hummel, teaches DH and the sources of DH. The source, the gene, and the E.C number of DH are not limitations under the US patent practice. They are inherent properties of DH and the choice of one DH over another is an obvious selection available to the preference of an artisan. Therefore, the instant invention is prima facie obvious from the teachings of the prior arts. One of ordinary skill in the art would have known to use hydrogen halide and DH in the process of Kuniyoshi et al., and/or Dieter et al., at the time the invention was made. The motivation is from the teaching of the prior arts.

Alternatively, given the teachings of the prior arts, it would have been obvious to try hydrogen halide and DH in the process of Kuniyoshi et al., and/or Dieter et al., at the time the invention was made.

When there is motivation

to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under [35 USC] 103.

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727,-----, 82 USPQ2d 1385, 1397 (2007).

Alternatively, the instantly claimed process of making formula III, its stereo selective reduction with DH to formula IV, and conversion of IV to formula I are not applicant's invention. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function it did no more than what they would have done separately. *In re Anderson*, 396 U.S. 57, 163 USPQ

673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007).

When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

Alternatively, applicant has done nothing more than substitutes hydrogen halide and DH in the process of Kuniyoshi et al., or Dieter et al. However, such substitution is obvious from the prior arts. "When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *United States v. Adams*, 383 U.S. 49, 50-51 (1966). Cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR, supra*.

Alternatively, given the teachings of the prior arts, one of ordinary skill faced with the need to make 3-methylamino-1-(thienyl-2-yl)propan-1-ol would have known to use hydrogen halide and DH at the time the invention was made. "When a work is available in one field of endeavour, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technology is obvious unless its actual application is beyond his or her skill." "One of the

ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007).

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-11, 21-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, of copending Application No. 10/552,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the compounds made in the instant application are made in the co-pending application, the difference being the scopes. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Figures and Specification

The lines in figures 1, 2A and 2B are not clear. The figures appear to be informal copies. The specification does not have sub-headings, such as, title, b/background, brief summary, brief description of drawing, detail summary, etc. New figures and specification are required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish above it.

**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1625

December 6, 2007